

IAEA SAFETY STANDARDS SERIES

Organization and Staffing of the Regulatory Body for Nuclear Facilities

SAFETY GUIDE

No. GS-G-1.1



INTERNATIONAL
ATOMIC ENERGY AGENCY
VIENNA

IAEA SAFETY RELATED PUBLICATIONS

IAEA SAFETY STANDARDS

Under the terms of Article III of its Statute, the IAEA is authorized to establish standards of safety for protection against ionizing radiation and to provide for the application of these standards to peaceful nuclear activities.

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ORGANIZATION AND STAFFING
OF THE REGULATORY BODY
FOR NUCLEAR FACILITIES

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The Agency's Statute was approved on 23 October 1956 by the Conference on the Statute of the IAEA held at United Nations Headquarters, New York; it entered into force on 29 July 1957. The Headquarters of the Agency are situated in Vienna. Its principal objective is "to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world".

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FOREWORD

**by Mohamed ElBaradei
Director General**

One of the statutory functions of the IAEA is to establish or adopt standards of safety for the protection of health, life and property in the development and application of nuclear energy for peaceful purposes, and to provide for the application of these standards to its own operations as well as to assisted operations and, at the request of the parties, to operations under any bilateral or multilateral arrangement, or, at the request of a State, to any of that State's activities in the field of nuclear energy.

The following bodies oversee the development of safety standards: the Commission on Safety Standards (CSS); the Nuclear Safety Standards Committee (NUSSC); the Radiation Safety Standards Committee (RASSC); the Transport Safety Standards Committee (TRANSSC); and the Waste Safety Standards Committee (WASSC). Member States are widely represented on these committees.

In order to ensure the broadest international consensus, safety standards are also submitted to all Member States for comment before approval by the IAEA Board of Governors (for Safety Fundamentals and Safety Requirements) or, on behalf of the Director General, by the Publications Committee (for Safety Guides).

The IAEA's safety standards are not legally binding on Member States but may be adopted by them, at their own discretion, for use in national regulations in respect of their own activities. The standards are binding on the IAEA in relation to its own operations and on States in relation to operations assisted by the IAEA. Any State wishing to enter into an agreement with the IAEA for its assistance in connection with the siting, design, construction, commissioning, operation or decommissioning of a nuclear facility or any other activities will be required to follow those parts of the safety standards that pertain to the activities to be covered by the agreement. However, it should be recalled that the final decisions and legal responsibilities in any licensing procedures rest with the States.

Although the safety standards establish an essential basis for safety, the incorporation of more detailed requirements, in accordance with national practice, may also be necessary. Moreover, there will generally be special aspects that need to be assessed on a case by case basis.

The physical protection of fissile and radioactive materials and of nuclear power plants as a whole is mentioned where appropriate but is not treated in detail; obligations of States in this respect should be addressed on the basis of the relevant instruments and publications developed under the auspices of the IAEA. Non-radiological aspects of industrial safety and environmental protection are also not explicitly considered; it is recognized that States should fulfil their international undertakings and obligations in relation to these.

The requirements and recommendations set forth in the IAEA safety standards might not be fully satisfied by some facilities built to earlier standards. Decisions on the way in which the safety standards are applied to such facilities will be taken by individual States.

The attention of States is drawn to the fact that the safety standards of the IAEA, while not legally binding, are developed with the aim of ensuring that the peaceful uses of nuclear energy and of radioactive materials are undertaken in a manner that enables States to meet their obligations under generally accepted principles of international law and rules such as those relating to environmental protection. According to one such general principle, the territory of a State must not be used in such a way as to cause damage in another State. States thus have an obligation of diligence and standard of care.

Civil nuclear activities conducted within the jurisdiction of States are, as any other activities, subject to obligations to which States may subscribe under international conventions, in addition to generally accepted principles of international law. States are expected to adopt within their national legal systems such legislation (including regulations) and other standards and measures as may be necessary to fulfil all of their international obligations effectively.

EDITORIAL NOTE

An appendix, when included, is considered to form an integral part of the standard and to have the same status as the main text. Annexes, footnotes and bibliographies, if included, are used to provide additional information or practical examples that might be helpful to the user.

The safety standards use the form 'shall' in making statements about requirements, responsibilities and obligations. Use of the form 'should' denotes recommendations of a desired option.

The English version of the text is the authoritative version.

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1. INTRODUCTION

BACKGROUND

1.1. The achievement and maintenance of a high level of safety in the siting, design, construction, commissioning, operation and decommissioning of nuclear facilities, and in the closure of waste disposal facilities, requires a sound legal and governmental infrastructure. An appropriately organized and staffed independent regulatory body with well defined responsibilities and functions and access to adequate resources is a key element of such an infrastructure.

1.2. The IAEA Safety Requirements publication on Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety [1] sets out the requirements for such an infrastructure. These include requirements in respect of the establishment of an independent regulatory body for nuclear facilities and the responsibilities and functions to be assigned to it.

1.3. Four interrelated IAEA Safety Guides provide recommendations on satisfying the requirements concerning particular responsibilities and functions of the regulatory body in the regulation of nuclear facilities. The present Safety Guide addresses the organization and staffing of the regulatory body; three related Safety Guides cover, respectively, regulatory review and assessment [2], regulatory inspection and enforcement [3] and documentation relating to the regulatory process [4].

OBJECTIVE

1.4. The purpose of this Safety Guide is to provide recommendations for national authorities on the appropriate management system, organization and staffing for the regulatory body responsible for the regulation of nuclear facilities in order to achieve compliance with the applicable safety requirements.

SCOPE

1.5. This Safety Guide provides recommendations on the organization and staffing of a regulatory body for nuclear facilities: its structure and organization; its interaction with other organizations; the appropriate qualifications required of the staff of the regulatory body; and the training to be provided for those staff.

1.6. The present Safety Guide covers the organization and staffing in relation to nuclear facilities such as: enrichment and fuel manufacturing plants; nuclear power plants; other reactors such as research reactors and critical assemblies; spent fuel reprocessing plants; and radioactive waste management facilities such as treatment, storage and disposal facilities. This Safety Guide also covers issues relating to the decommissioning of nuclear facilities, the closure of waste disposal facilities and site rehabilitation.

STRUCTURE

1.7. Section 2 of this Safety Guide provides recommendations on regulatory independence and funding of the regulatory body. Section 3 presents recommendations on an organizational framework for the regulatory body carrying out its statutory functions. Recommendations on staffing of the regulatory body are given in Section 4. Section 5 addresses the initial and continuing training needs. The Appendix gives the basic elements of a regulatory training programme.

2. REGULATORY INDEPENDENCE AND FUNDING OF THE REGULATORY BODY

GENERAL

2.1. Legislative and governmental responsibilities and a number of prerequisites for the safety of nuclear facilities and activities are addressed in Section 2 of the Safety Requirements publication on Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety [1]. Some of the prerequisites, such as the legislative and statutory framework, infrastructure, responsibilities and authorities, are covered in Ref. [1]. Other prerequisites concerned with the main functions of the regulatory body are covered in Refs [2–4]. This section provides recommendations on two of these prerequisites, namely regulatory independence and the funding of the regulatory body.

REGULATORY INDEPENDENCE

2.2. The importance of regulatory independence is affirmed in the Convention on Nuclear Safety¹ [5] and in the IAEA Safety Requirements [1]. Both deal with the establishment of a regulatory body and the need for its separation or independence from promoters of nuclear technologies. The primary reason for this independence is to ensure that regulatory judgements can be made and regulatory enforcement actions taken without pressure from interests that may conflict with safety. Furthermore, the credibility of the regulatory body to the general public depends in large part upon whether the regulatory body is considered to be independent of the organizations that it regulates as well as independent of governmental organizations and industry groups that promote nuclear technologies.

2.3. It is recognized that a regulatory body cannot be absolutely independent in all respects of other parts of government: it must function within a national system of laws and budgets, just as other governmental bodies and private organizations must do. Nevertheless, for the regulatory body to have credibility and effectiveness, it should have effective independence in order to be able to make the necessary decisions in respect of the radiological protection of workers, the public and the environment.

2.4. The need for independence of the regulatory body does not imply that it ought to have an adversarial relationship with operators or with any other party.

2.5. The following paragraphs provide a more detailed discussion of a number of aspects of regulatory independence.

Aspects of regulatory independence

2.6. *Political aspects.* The political system shall ensure clear and effective separation of responsibilities and duties between the regulatory body and organizations promoting or furthering the development of nuclear technologies. In this regard, a distinction should be made between independence and accountability. The regulatory

¹ Article 8.2 of the Convention on Nuclear Safety requires: "...an effective separation between the functions of the regulatory body and those of any other body or organization concerned with the promotion or utilization of nuclear energy." The IAEA's Safety Requirements publication on Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety stipulates that "[a] regulatory body... shall be effectively independent of organizations or bodies charged with the promotion of nuclear technologies or responsible for facilities or activities." (Ref. [1], para. 2.2 (2).)

body should not be subject to political influence or pressure in taking decisions relating to safety. The regulatory body should, however, be accountable in respect of fulfilling its mission to protect workers, the public and the environment from undue radiation hazards. One way of ensuring this accountability is to establish a direct reporting line from the regulatory body to the highest levels of government. Where a regulatory body is part of an agency or organization that has responsibility for exploiting or promoting the development of nuclear technologies, there should be channels of reporting to high authorities that have safety as one of the primary missions and to which it is clearly accountable when resolving conflicts of interest that may arise. This accountability should not compromise the independence of the regulatory body in making specific decisions relating to safety with neutrality and objectivity.

2.7. *Legislative aspects.* The functions and independence of the regulatory body in respect of safety shall be defined in the legislative framework of a national regulatory system (that is, in the laws or decrees relating to nuclear energy). The regulatory body shall have the authority to adopt or to develop regulations relating to safety that give effect to laws enacted by the legislature. The regulatory body shall also have the authority to take decisions, including decisions on enforcement actions. There shall be a formal mechanism for appeal against regulatory decisions, with predefined conditions that must be met for an appeal to be considered.

2.8. *Financial aspects.* “The regulatory body shall be provided with adequate authority and power, and it shall be ensured that it has adequate staffing and financial resources to discharge its assigned responsibilities.” (Ref. [1], para. 2.2 (4)). While it is recognized that the regulatory body is in principle subject to the same financial controls as the rest of government, the budget of the regulatory body should not be subject to review and approval by government agencies responsible for exploiting or promoting the development of nuclear technologies.

2.9. *Competence aspects.* The regulatory body should have independent technical expertise in the areas relevant to its responsibilities for safety. The management of the regulatory body should therefore have the responsibility and authority to recruit staff with the skills and technical expertise it considers necessary to carry out the regulatory body’s functions. In addition, the regulatory body should maintain an awareness of developments in safety related technology. In order to have access to external technical expertise and advice that is independent of any funding or support from operators or from the nuclear industry to assist it in its decision making on regulatory matters, the regulatory body shall (Ref. [1], para. 2.4 (9)) have the authority to set up and fund independent advisory bodies to provide expert opinion and advice and to award contracts for research and development projects. In particular, the regulatory body shall be able “to obtain such documents and opinions

from private or public organizations or persons as may be necessary and appropriate” (Ref. [1], para. 2.6 (10)).

2.10. *Public informational aspects.* One of the responsibilities of the regulatory body should be to inform the public. “The regulatory body shall have the authority to communicate independently its regulatory requirements, decisions and opinions and their basis to the public” (Ref. [1], para. 2.6 (11)). The public will only have confidence in the safe use of nuclear technologies if regulatory processes are conducted and decisions are made openly. The governmental authorities should set up a system to allow independent experts and experts representing major stakeholders (for example, the nuclear industry, the workforce and the public) to provide their views on safety and related issues. The experts’ findings should be made public.

2.11. *International aspects.* “The regulatory body shall have the authority to liaise with regulatory bodies of other countries and with international organizations to promote co-operation and the exchange of regulatory information.” (Ref. [1], para. 2.6 (14).)

FUNDING OF THE REGULATORY BODY

2.12. According to the Safety Requirements (Ref. [1], para. 2.2 (4)), the regulatory body shall be adequately funded so as to be able to function effectively. Specific provisions to accomplish this should be established through implementing legislation or through the national fiscal process. How this is best accomplished will depend on a number of considerations and factors, including:

- national precedents for funding other regulatory organizations;
- the types and scale of regulated facilities;
- how the regulatory body is structured: whether free standing, a component of a larger organization or with functions and responsibilities divided between two or more governmental organizations.

2.13. In setting the level of funding for a regulatory body, the need for offices and office equipment, the salaries of staff, and the costs of communications, transport, inspection equipment, training and related materials should be taken into account. In addition, the funding should cover the costs of research and development, consultancy services and international co-operation, as appropriate.

2.14. The regulatory body should be funded by the government or by means of the recovery of costs from operators, or by some combination of the two.

2.15. If a State has an established nuclear power programme, the costs of the regulatory body could be recovered in whole or in part through fees. The costs of the preparation of a licence, review and assessment, inspection, and the development of regulations and guides could be recovered through fees, whereas certain other activities of the regulatory body, such as participation in international activities, could be funded by other means.

2.16. Where the regulatory body levies charges for licences, a direct link between the funds generated and the regulatory body's budget should be avoided. For example, fees might be channelled to a 'nuclear fund' established for this purpose or directly to the national treasury. This helps to counter challenges to the basis for charges, as well as challenges to the independence of the regulatory body.

2.17. In order to prevent abuses or the appearance of abuses on the part of the regulatory body, fines levied in respect of enforcement actions should not be used to contribute to the funding of the regulatory body.

3. ORGANIZATION OF THE REGULATORY BODY

GENERAL

3.1. "The regulatory body shall be structured so as to ensure that it is capable of discharging its responsibilities and fulfilling its functions effectively and efficiently. The regulatory body shall have an organizational structure and size commensurate with the extent and nature of the facilities and activities it must regulate, and it shall be provided with adequate resources and the necessary authority to discharge its responsibilities. The structure and size of the regulatory body are influenced by many factors, and it is not appropriate to require a single organizational model. The regulatory body's reporting line in the governmental infrastructure shall ensure effective independence from organizations or bodies charged with the promotion of nuclear or radiation related technologies, or those responsible for facilities or activities." (Ref. [1], para. 4.1.)

3.2. A regulatory body, its structure and size, and the technical skills of its staff will change as the regulatory body passes through various phases, starting with its early organization and the preparation of its regulatory foundation to the stage where it is considered fully operational. The structure and composition of the regulatory body

should be adapted in the course of time for it to be able to act effectively and to address key issues that arise at any time during the siting, design, construction, commissioning, operation and decommissioning of nuclear facilities, or closure in the case of waste disposal facilities.

3.3. The organizational structure of the regulatory body may differ from State to State, depending on the national legal system and practices. This Safety Guide provides general guidance on the organizational structure on the basis of the functions of the regulatory body, but it is recognized that alternative structures may also be effective in providing adequate regulation of matters relating to safety.

3.4. The principal functions to be performed by the regulatory body are: the development of regulations and guides; review and assessment; authorization; and inspection and enforcement. The regulatory body will also have functions and responsibilities in respect of emergency preparedness and public information. In addition, feedback on operational experience provides important information for the safe operation of nuclear facilities. The regulatory body should therefore be organized to take full advantage of lessons learned from the feedback of operational experience both from facilities in its own country and from those in other States. In a large organization, each of its functions may be assigned to a discrete organizational unit within the regulatory body. Each organizational unit may have its own specialists. However, it is often practical and efficient to group the specialists in a matrix such that each organizational unit that is assigned responsibility for a particular function can draw on the necessary specialist skills. There is a particular need for interaction and integration between assessment and inspection functions.

3.5. The regulatory body may also have additional functions, such as independent radiological monitoring in and around nuclear facilities, and initiating, co-ordinating and monitoring safety related research and development work in support of its regulatory functions.

3.6. “If the regulatory body is not entirely self-sufficient in all the technical or functional areas necessary to discharge its responsibilities for review and assessment or inspection, it shall seek advice or assistance, as appropriate, from consultants. Whoever may provide such advice or assistance (such as a dedicated support organization, universities or private consultants), arrangements shall be made to ensure that the consultants are effectively independent of the operator. If this is not possible, then advice or assistance may be sought from other States or from international organizations whose expertise in the field concerned is well established and recognized.” (Ref. [1], para. 4.3.)

3.7. In order for a regulatory body to be effective in discharging its responsibilities, additional expertise should be obtained in terms of administrative support, legal assistance, consultants, advisory committees and assistance for public information, as well as provisions for regular contact with other bodies both nationally and internationally.

3.8. Whatever the organizational structure of the regulatory body, a decision should be made as to whether all the staff will work from a single location or whether a central headquarters will be established with some staff located in different regions of the State. In the decision, factors such as the type and geographical spread of the facilities, the ease and cost of travel to sites, the need to be close to other governmental organizations, the amount of time inspectors need to spend on site to fulfil their duties and the proximity of dedicated support organizations should be considered.

MANAGEMENT SYSTEM WITHIN THE REGULATORY BODY

3.9. For a regulatory body to fulfil its statutory obligations, it should develop a regulatory management system with the necessary arrangements for achieving and maintaining a high quality of performance in regulating the safety of nuclear facilities under its authority.

3.10. Many aspects of the regulatory management system are common to the management of public and private organizations in general. The development of an effective and efficient regulatory management system requires a clear understanding of the different functions and responsibilities of the regulatory body and of the operating organizations in respect of safety. In developing the regulatory management system, the regulatory body should identify its main functions and should take into account support functions and control functions derived from the main functions.

REGULATIONS AND GUIDES

3.11. If new or revised regulations and guides are needed frequently, establishing a permanent organizational unit for this purpose should be considered. Where the need for new or revised regulations and guides is infrequent, it may be sufficient to put in place a mechanism whereby such resources can be drawn upon when necessary. The most knowledgeable people should be deployed for the task of producing regulations and guides, which form the basis of all the activities of the regulator.

3.12. The production of regulations and guides should be undertaken with full consultation both within and outside the regulatory body. Thus an opportunity should

be provided for review and comment by relevant government departments, other regulatory authorities, affected operators and other interested parties and, if appropriate, through consultation with the public.

3.13. In developing regulations and guides, account should be taken of international standards and recommendations, obligations imposed by any conventions to which the State may be party, relevant industrial standards and any advances in technology. Consideration should also be given to regulations and guides from other States as this may reduce the workload on the regulatory body in the drafting process. Further details are provided in Ref. [4].

REVIEW AND ASSESSMENT

3.14. Review and assessment are among the main continuous functions of a regulatory body. The responsibility for review and assessment should be assigned to a person or an organizational unit of the regulatory body. Review and assessment often necessitate forming teams of specialists, depending on the complexity of the facility under review and the scale and nature of the review and assessment work. These teams of specialists may be organized into a discrete part of the regulatory body or may be formed as and when needed. In either case a supervisor or project manager should be appointed to coordinate the work. If sufficient expertise is not available within the regulatory body, part of the review and assessment activities may be contracted out, for example, to a dedicated support organization or a consultant (see para. 3.28).

3.15. Review and assessment should be carried out in accordance with principles and criteria set out in regulations and guides. The review and assessment work necessitates effective communication and interaction between different units of the regulatory body. The main parameters, characteristics and results of review and assessment should be recorded and retained, in written form, for future reference. Further details on review and assessment are given in Ref. [2].

AUTHORIZATION

3.16. Authorization is the principal mechanism connecting the laws and regulations which form the legal framework of the regulatory system with the responsibilities of the principal parties concerned (the regulatory body and the operator). The regulatory body should be organized to enable it to conduct the authorization process efficiently (see the Appendix of Ref. [4] on the authorization process). The regulatory body shall keep records of authorization and shall retain the relevant documents in connection

with the authorization process (Ref. [1], para. 5.5). For details of the necessary documentation, see Ref. [4]. In some States public consultation is considered an integral part of the overall authorization process.

INSPECTION

3.17. A dedicated organizational unit for the co-ordination of inspection activities should be considered, and is merited in most cases. Inspections may concern particular aspects of a facility, and may be undertaken by an individual inspector or by a team of inspectors. They may include a visit to a facility by a group of specialists. Project managers or supervisors should be appointed to plan and monitor the work for all inspections performed for a particular facility and to compile the results.

3.18. The organization of inspections will depend on the scale of the activities and the availability of specialist personnel. If sufficient expertise is not available within the regulatory body, part of the inspection activities may be performed under contract under the supervision of the regulatory body's personnel.

3.19. An inspection may result in a requirement for additional review and assessment or for enforcement actions. For this reason, irrespective of how inspections are organized, there should be strong and effective links with all other units of the regulatory body. Written inspection reports should be prepared and, where appropriate, the conclusions should be communicated to the organization that has been inspected. Further details are given in Ref. [3].

Resident and non-resident inspectors

3.20. The use of resident inspectors may provide benefits such as improving the ability of the regulatory body to engage in on-site surveillance of systems, components, tests, processes and other activities of the operator at any time. The full time presence of inspectors may also help to discourage complacency or non-compliance on the part of the operator and can improve the ability of the regulatory body to identify and respond promptly to problems. With resident inspectors, the frequency and intensity of inspections for any given level of human resources can be more readily optimized, and the regulatory body may be better informed of the operator's schedules and hence better able to co-ordinate its inspection activities with key operator activities to be observed. A factor to be considered is the physical distance between a non-resident inspector and the facility. This has implications for resources in terms of costs, inspectors' time and the time for response to unforeseen circumstances. The use of resident inspectors

may also be dependent on the extent to which outside consultants or dedicated support organizations are contracted by the regulatory body to perform inspections at the site. The responsibilities and practices of both resident and non-resident inspectors should be defined in a manner that does not diminish the operator's responsibility for safety.

3.21. The use of non-resident inspectors may demand less in terms of human resources than the use of resident inspectors. Non-resident inspectors may inspect more than one site, which may be a more efficient use of limited resources. Alternatively, a non-resident inspector may be assigned to a particular facility and may co-ordinate inspection activities at that facility. Non-resident inspectors may be more readily available to assist the regulatory body in discharging its responsibilities for review and assessment and authorization. The objectivity of a non-resident inspector is less likely to be compromised in dealing with the operator. Furthermore, a non-resident inspector is less likely to become unduly isolated from the activities and decision making of the regulatory body.

3.22. To assist inspectors in maintaining objectivity and independence, consideration should be given to changing the facility to which they are assigned from time to time or giving them general duties at headquarters. Where resident inspectors are employed, consideration should be given to locating more than one at a particular site for mutual support. There should be adequate communication between resident inspectors and headquarters in order to maintain their regulatory effectiveness.

ENFORCEMENT

3.23. The conduct of review and assessment and inspection, as well as regulatory review of reports by the operators and audits, can result in the detection of non-compliance by the operator. The organizational structure of the regulatory body should enable enforcement actions to be taken consistently and objectively. The degree of authority given to an inspector may depend on the structure of the regulatory body and on the inspector's role and experience.

EMERGENCY PREPAREDNESS

3.24. The regulatory body shall ensure that operators have adequate arrangements for emergency preparedness (see Ref. [1], para. 3.2(3)). Again, depending on the size of the organization, this can be undertaken by a separate unit, but is more likely to be part of the inspection or review and assessment function.

3.25. The exact role of the regulatory body in emergencies varies considerably between States, depending on how it is organized to respond to emergencies in general. In many States the regulatory body has an advisory function for the authority responsible for emergency preparedness. In all but the largest of organizations, the allocation of dedicated resources for this function is unlikely to be justified. Adequate procedures should therefore be prepared to obtain the requisite resources as necessary and to deploy them as appropriate. The organizational structure of the regulatory body should clearly indicate the responsible person or group in charge of co-ordinating the development of procedures, liaising with other organizations for emergency preparedness and conducting exercises. For further details see Ref. [6].

ADMINISTRATIVE SUPPORT

3.26. The regulatory body should have either a number of individuals or an organizational unit dedicated to general administrative work. The number of individuals or the size of the unit should depend on the size of the regulatory body. Administrative support includes the following activities:

- Personnel administration, which covers recruitment and training, internal information, arrangements for medical care, travel arrangements and so on;
- Other administrative tasks such as computer and/or data administration and library services, including access to specialized publications;
- Management of documentation, including the preparation, storage, retrieval, reproduction and distribution of documents;
- Preserving the ‘corporate memory’;
- General administration such as internal planning, maintenance of buildings and equipment, operation of communication systems and security;
- Financial administration, including procurement, accounting, salaries and invoicing.

LEGAL ASSISTANCE

3.27. A regulatory body by its nature is engaged in activities that require professional legal assistance. The legal assistance can be provided by the staff of the regulatory body or by another government body, or can be obtained under contract. The regulatory body should be structured to reflect either implicitly or explicitly the interface of legal functions with technical and managerial functions. Activities typically requiring professional legal participation include:

- development of basic legislation;
- development of regulations and review for compatibility with the national legal system;
- ensuring the compatibility of the regulations by reviewing drafts of legislative documents;
- ensuring that national legislation is compatible with international conventions and agreements;
- assisting in the development of the internal administrative procedures of the regulatory body;
- providing legal advice in the authorization process;
- providing legal advice on proposed enforcement actions;
- representing the regulatory body in the event of enforcement activities;
- representing the regulatory body at the court of law;
- assisting the technical units and public information officers, if designated, in responding to requests for public information.

CONSULTANTS

3.28. If a regulatory body or its dedicated support organization does not have an adequate number of qualified personnel or an adequate diversity of technical skills, or if the workload does not justify the recruitment of full time staff, consultants may be used to perform selected tasks. The technical qualifications and experience of such consultants should be at the same level as or greater than those of the staff of the regulatory body who are performing similar tasks. More generally, consultants are used by the regulatory body to assist in performing tasks that necessitate an additional level or area of expertise, which may arise occasionally, or to provide a second opinion on important issues.

3.29. Since the regulatory body has to evaluate and utilize the work performed by consultants, it should define the scope of the work to be performed. The consultant should be required to provide a detailed written report. Such reports should include the basis for and the method of the consultant's evaluation, the conclusions and any related recommendations that may assist the regulatory body. Several points should be noted in connection with the use of consultants:

- The regulatory body's staff should have sufficient technical knowledge to enable them to identify problems, to determine whether it would be appropriate to seek assistance from a consultant and to evaluate the consultant's advice.
- It is the regulatory body's responsibility to evaluate the advice of consultants and to determine whether and how it is to be adopted.

- Consultants should be chosen so that they are able to provide impartial advice. It should be confirmed that the consultant’s other activities as a specialist do not give rise to a bias in the advice given; the potential for any such conflict of interest should be recognized and minimized.

ADVISORY COMMITTEES

3.30. The government or the regulatory body may choose to give formal structure to the processes by which expert opinion and advice are provided to the regulatory body. For example, broadly based advisory committees with membership drawn from other government departments, regulatory bodies of other States, scientific organizations and the industry that is regulated can bring broad perspectives to bear on the formulation of regulatory policy and regulations. A well founded committee can render valuable service to the regulatory body by helping to ensure that policies and regulations are clear, practical and complete, and provide a good balance between the regulated industry’s interests and the need for strict regulatory control.

3.31. Another type of advisory committee is the technical committee composed of members with a range of technical skills necessary to evaluate complex technical issues. Such committees may have a defined role in the authorization process. Alternatively, they may be ad hoc, performing a function similar to that of consultants, but dealing with complex issues for which a number of different skills are necessary. “Any advice offered shall not relieve the regulatory body of its responsibilities for making decisions and recommendations.” (Ref. [1], para. 4.9.)

3.32. Many of the points set out in para. 3.28 in connection with the use of consultants apply also to the membership of and use of advisory committees, but with one additional factor. Well before a committee is established, clearly defined terms of reference should be prepared and specific criteria for the selection of its membership should be drawn up. This will reduce the likelihood of subsequent controversy about the role of the committee and its constitution. The committees should have well focused agenda for their meetings, including deadlines for their deliberations in order for them to give timely advice.

RESEARCH AND DEVELOPMENT

3.33. The regulatory body should encourage facility operators to carry out the research and development necessary to produce an adequate body of knowledge

about safety. However, there may be situations in which the operator's research and development are insufficient or in which the regulatory body requires independent research and development to confirm specific important findings. The regulatory body may need to conduct or commission research and development work in support of its regulatory functions in such areas as inspection techniques and analytical methods or in developing new regulations and guides.

3.34. The organizational structure of the regulatory body should reflect these needs for research and development, either by the establishment of a research unit or by recruiting staff who can define research and development needs, initiate, co-ordinate and monitor the necessary work, and evaluate the results. Regardless of how the research is carried out, the regulatory body should ensure that it is focused on regulatory needs, whether in the short or long term, and that the results are disseminated to the appropriate organizational units.

LIAISON WITH OTHER ORGANIZATIONS

3.35. The actions and responsibilities of many organizations at different levels of government can interact with those of the regulatory body. Such organizations may include:

- environmental protection authorities;
- authorities responsible for public liability issues;
- authorities for physical protection and/or safeguards;
- authorities for planning water resources and land use;
- authorities responsible for public and occupational health and safety;
- fire protection authorities;
- transport authorities;
- law enforcement bodies;
- bodies with responsibility for civil engineering structures and buildings, and electrical and mechanical equipment.
- other bodies with responsibilities for emergency preparedness;
- other bodies with responsibilities for limits on releases of radioactive effluents;
- other regulatory authorities, particularly those performing similar functions.

3.36. As governments take actions to ensure that various hazards are properly regulated, it is inevitable that there may be some interface between the responsibilities of regulatory authorities. Where the responsibilities of regulatory authorities and other organizations interact or have an interface, good liaison between these bodies should be established by means of a formal agreement specifying each

organization's responsibilities, the areas of interface and the means of resolving any conflicts between different requirements. It should be ensured that no conflicting requirements are placed upon an operator. In many cases, regular liaison meetings should be held between the organizations concerned.

3.37. To help promote a better working relationship with other organizations, the regulatory body should assign responsibilities for making arrangements for liaison to an individual or an organizational unit. All staff members of the regulatory body should be made aware of the reasons for and the implications of the overlapping responsibilities and of the fact that good working relationships at all levels are necessary.

3.38. The regulatory body should be so organized as to be capable of providing operators and other governmental organizations with clear, accurate and timely information in areas relevant to its responsibilities. Details of the relationship between the regulatory body and the operator, its contractors and other organizations involved in the review and assessment process are given in Ref. [2].

PUBLIC INFORMATION

3.39. The regulatory body should be organized to provide public information concerning its activities, both on a regular basis and in relation to abnormal events. Information provided to the public should be factual and as objective as possible, reflecting the regulatory body's independence. The regulatory body should be as open as possible while complying with national legislation on confidentiality. Public information should be managed by individuals with expertise in the field so as to ensure that the information provided is clear and comprehensible. In a large regulatory body, the establishment of a specialized public information unit should be considered.

INTERNATIONAL CO-OPERATION

3.40. "The safety of facilities and activities is of international concern. Several international conventions relating to various aspects of safety are in force. National authorities, with the assistance of the regulatory body, as appropriate, shall establish arrangements for the exchange of safety related information, bilaterally or regionally, with neighbouring States and other interested States, and with relevant intergovernmental organizations, both to fulfil safety obligations and to promote co-operation." (Ref. [1], para. 4.11.)

3.41. International co-operation by the regulatory body, arranged by means of multilateral or bilateral agreements, may include exchange of information, mutual assistance in regulatory activities, staff training and regular staff meetings on specific subjects and other matters. Multilateral co-operation may involve different approaches, for example, regional approaches, multilateral approaches based on the design or type of the facilities concerned and approaches on the basis of common problems concerning safety.

3.42. The regulatory body may also assist in fulfilling national obligations under international conventions. These obligations may require follow-up actions on the part of the regulatory body as appropriate.

3.43. The regulatory body should participate in the preparation of international standards and may also serve as the contact body for international systems for the exchange of safety related information (such as the Incident Reporting System of the IAEA and the Nuclear Energy Agency of the Organisation for Economic Co-operation and Development) in order to ensure the quality of information provided to these systems and to ensure the communication of information to and from operators and other governmental organizations.

4. STAFFING

GENERAL

4.1. “The regulatory body shall employ a sufficient number of personnel with the necessary qualifications, experience and expertise to undertake its functions and responsibilities. It is likely that there will be positions of a specialist nature and positions needing more general skills and expertise. The regulatory body shall acquire and maintain the competence to judge, on an overall basis, the safety of facilities and activities and to make the necessary regulatory decisions.” (Ref. [1], para. 4.6.)

4.2. Regulatory staff should have appropriate academic qualifications, preferably combined with experience in the operation of the facilities to be regulated and in nuclear technology, or with related experience. The regulatory body as a whole as well as individual staff members should undergo a continuous learning process from the time of its establishment. Furthermore, as a regulatory body matures and its workforce ages, particular attention should be paid to succession planning for key

managers and senior technical staff. The introduction of new types of facility, the introduction of novel technology, the ageing of facilities or the passage of a facility to another phase of its service life may all present challenges to the regulatory body, since its staff may have had little or no relevant experience. The expertise which is necessary for the regulatory body's staff when the programme is more mature may differ from that required at the outset of the programme.

4.3. The regulatory body should include staff with expertise in a wide range of technical matters and in human factors. The phase and scale of the nuclear programme should be considered in deciding how these disciplines are to be represented in the organizational set-up. The regulatory body should have enough experienced staff to be able to do basic regulatory work and to evaluate the quality and results of the work performed for it by consultants.

4.4. The staff of the regulatory body will be expected to co-ordinate and manage various activities of the regulatory programme, some of which may be performed by the regulatory staff and others with the assistance of consultants, dedicated support organizations and advisory committees. Therefore some staff should have experience in technical programme management or project management.

4.5. The regulatory body should establish and maintain communication and a good working relationship with other governmental, professional and private organizations at the national and international levels. For this reason, members of the regulatory staff should have up to date knowledge of the responsibilities and structures of these organizations and should maintain contacts with their personnel.

4.6. In addition to working in an appropriate legal framework and employing sufficient staff with suitable qualifications and expertise, the effectiveness of the regulatory body will depend also on the status of its staff in comparison with that of the staffs of both the operator and the other organizations involved. Members of the regulatory body staff should therefore be appointed at such grades and with such salaries and conditions of service as would facilitate their regulatory relationships and reinforce their authority.

RECRUITMENT

4.7. The senior management of the regulatory body should review the functions that are required to be performed and should determine the size and composition necessary for the regulatory body to be able to fulfil its obligations. The appropriate size for a regulatory body will depend on a range of factors: the various types and the number of facilities, the number of operating organizations, the regulatory approach

adopted and the legal arrangements in place. Regulatory bodies in different States are of widely different sizes because of these factors². The senior management of the regulatory body should decide how best to fill vacant posts, having determined which skills and knowledge are lacking in its personnel and which are available in the labour market. If recruits with the necessary skills and knowledge are in short supply, it may be appropriate to establish a training programme to develop the skills of new recruits or existing staff. In this approach, it should be determined which training requirements are essential and how they can be met.

4.8. Work experience is an important consideration in selecting personnel to staff the regulatory body. If the nuclear programme is just being established, the sources for recruitment may be limited, but States with established nuclear research institutes often look to these institutes for personnel with experience in the nuclear field. Where a nuclear programme is well established, staff can be recruited to the regulatory body from many sources, including the operating organizations. Arrangements should be made to ensure that recruits from organizations in the nuclear industry are not placed in roles in which they might compromise the independence of the regulatory body. Sufficient time should be allowed to elapse to ensure that the recruits no longer have an affiliation with the organization from which they were recruited.

4.9. It should be considered whether it is appropriate to develop a future supply of suitable potential recruits, for example, by encouraging and supporting relevant courses at academic institutions. It is useful to involve the staff of the regulatory body in the provision of such courses with a view to passing on to the students practical knowledge as applied by the regulatory body and keeping the staff's knowledge updated. New recruits should be assigned only limited tasks and should work under supervision until they have completed the initial period of their training and an evaluation of their performance has been made.

QUALIFICATIONS OF STAFF

4.10. In the following paragraphs, the technical qualifications necessary for performing regulatory functions are discussed. In general, the recommendations on

² A survey conducted in 1987 of bodies regulating nuclear reactors showed that the level of staffing of the regulatory body was generally between 5 and 25 professional staff for each reactor under the body's authority (Analysis of Replies to an IAEA Questionnaire on Regulatory Practices in Member States with Nuclear Power Programmes, IAEA-TECDOC-485, IAEA, Vienna (1988)).

qualifications refer to the regulatory staff engaged in the main functions of developing regulations and guides, review and assessment, inspection and enforcement. The staff of the regulatory body should have sufficient work experience in a function that is highly relevant to the tasks which they will be assigned in the regulatory organization. This work experience, complemented by the training provided (see Section 5), should prepare them for their future tasks. Staff in the regulatory body should also be able to express themselves clearly.

4.11. In addition to good academic qualifications, it is desirable for the personnel selected to have:

- adequate work experience in a related area;
- adequate knowledge of the types of facility and activities that are to be regulated (this can be achieved by means of an appropriate training programme).

Furthermore, it is desirable for some recruits to have:

- appropriate management experience and technical experience so as to be able to assess and to judge the effective co-ordination and management of large engineering concerns and quality assurance activities.

4.12. The regulatory body should also recruit staff suitably qualified in administration, personnel management, financial management, law and other matters. The qualifications of staff performing these functions are not covered in this Safety Guide.

Regulations and guides

4.13. Persons assigned to develop or revise regulations and guides should have a sufficient understanding of the relevant areas. These persons should also have sufficient knowledge of existing regulations and guides to ensure consistency and compatibility between them. The workload in this functional area can be adjusted by assigning specialists from other functional areas to prepare regulations and guides for which specialized technical experience and knowledge are required or by making use of groups of consultants.

4.14. A unit, whether permanent or temporary, producing regulations and guides should have access to personnel with:

- experience of the activities being regulated,
- experience of regulatory enforcement,
- knowledge of the regulatory structure,

- knowledge of the procedures for producing regulations and guides,
- legal expertise and knowledge of the legal basis for regulations.

4.15. Personnel responsible for the development and revision of regulations and guides should be capable of co-ordinating the work of specialists from various disciplines. As part of their activities, they should review developments in regulations and guides on a broader level to gain awareness of such developments.

Review and assessment

4.16. Regulatory personnel should be capable of performing reviews and making independent judgements. They should possess a good working knowledge of the various regulations and guides applicable in their area of work, and should have an understanding of the design and operation of the nuclear facility with which they are involved. A small number of personnel who work in this functional area may be recruited with little or no work experience.

Inspection

4.17. Regulatory inspection differs somewhat from other regulatory functions in that an inspector's principal activity takes place at the facility site, interviewing people, observing and evaluating activities, reviewing records and, where appropriate, making decisions and recommendations. All inspectors should be able to evaluate and discuss safety related issues with the operator and the operator's contractors. Regulatory inspectors should be able to interview people to obtain all the relevant information available, and should be able to review and evaluate logbooks and other documents to detect potential problems. In addition, personnel who are assigned to inspect major activities (manufacture of components, commissioning and initial operation of facilities) should have sufficient relevant work experience, preferably in nuclear facilities of a type similar to those they will be assigned to inspect. As part of the function they are performing, inspectors are routinely involved in compliance assurance activities. The inspectors should also have a thorough knowledge and a good understanding of the regulations and guides that are relevant to various areas of a facility and experience in their application. The inspectors should be aware of the main bases of the safety report for the facility, and in particular of the important safety systems and procedures and the limits and conditions for safe operation, in order to command the respect of the operator. Moreover, resident inspectors should be experienced and capable of working without direct supervision, and should have the necessary skills so as to be able to represent the regulatory body adequately without being drawn into the operator's decision making process.

5. TRAINING OF STAFF

GENERAL

5.1. “In order to ensure that the proper skills are acquired and that adequate levels of competence are achieved and maintained, the regulatory body shall ensure that its staff members participate in well defined training programmes. This training should ensure that staff are aware of technological developments and new safety principles and concepts.” (Ref. [1], para. 4.7.)

5.2. In order to apply this requirement, the regulatory body, depending on the number and complexity of the facilities that it is regulating, should have:

- a training policy;
- budgetary provisions for training;
- a formal training programme as part of its organizational structure, in which the operational needs and the long term need for specialists and managers are taken into account, with designated personnel responsible for the operation and evaluation of the programme;
- a training plan for each employee which is tailored to the employee’s needs and function in the regulatory body;
- procedures in place for periodic review and updating of the training programme to take into account the changing needs of the individual and of the organization, and scientific and technological developments.

5.3. The training requirements for regulatory personnel should be based on the functional areas that have been described in previous sections of this Safety Guide. One of the objectives of training is to develop the skills and knowledge of the staff of the regulatory body in order to widen their appreciation of the work being undertaken by themselves as well as others.

5.4. Training of personnel needs substantial resources in terms of both staff and monetary costs. Sufficient thought and time should be devoted to defining the necessary training requirements and to the establishment of an effective training programme. The specific skills and levels of knowledge that individuals or groups of individuals have to acquire in order to perform specific regulatory tasks should also be defined.

5.5. Efforts commensurate with the size of the regulatory body should be made to develop a systematic approach to the training of personnel in order to ensure

consistency in the conduct of regulatory activities, including the application of quality assurance principles to training.

5.6. The regulatory training programme should consist of a combination of self-study, formal training courses, workshops and seminars (organized by the regulatory body and provided by itself, by academic or professional organizations, by regulatory bodies of other countries or by the IAEA) and on the job training in the State or abroad.

5.7. The organization of training will depend on the size and resources of the regulatory body. A small and newly established regulatory body will need external support, whereas a large and experienced regulatory body may be self-sufficient. International exchange of information should be a part of continuing training in order to obtain new ideas for further development.

TRAINING NEEDS

5.8. The general experience of States with established regulatory bodies is that they can recruit personnel with the required academic qualifications and years of relevant work experience, as discussed in Section 4. However, unless recruitment is from another regulatory body, it is unlikely that they can recruit personnel with the specific skills and knowledge necessary for conducting regulatory functions

5.9. A regulatory training programme should include induction training for new staff to ensure that all staff have an adequate overview of the work they will be performing. Typically they may need to be introduced to the law, legal powers, policies, internal guidance and procedures of the regulatory body. Hence, soon after recruitment, each member of staff should be provided with a training plan to cover safety related matters that are specific to the nuclear facilities being regulated, such as general design criteria and design and operational characteristics. Career progression should be considered in preparing the training plans. The training plans, including, as appropriate, periodic retraining, should specify the nature of the training needed, its timing and sequence and where it is to be obtained, and the levels of competence to be achieved. The basic elements mentioned in the Appendix should be taken into account.

5.10. At a later stage, there will be a need for refresher training to maintain knowledge, especially if there is a job change, and to draw attention to important changes in the law, procedures or other matters. Lastly, there is developmental training, both technical and non-technical, to prepare staff for job changes and promotions. The Appendix gives a list of the basic elements of a regulatory training programme.

ADMINISTRATION OF TRAINING

5.11. The administration of training should be formalized and responsibilities should be assigned within the regulatory body. For an effective and systematic approach to training, the regulatory body should consider the establishment of a training unit, either as part of its organization or with the assistance of specialized institutes. The regulatory body should arrange for its staff to have access to laboratories which have the necessary equipment to teach specific techniques (such as destructive and non-destructive testing for material properties and defects) and also, desirably, nuclear reactor simulators.

Appendix

BASIC ELEMENTS OF A REGULATORY TRAINING PROGRAMME

The technical and non-technical elements of a regulatory training programme comprise:

- Basic knowledge of:
 - radiation and industrial safety;
 - relevant legislation;
 - principles of nuclear, radiation, waste and transport safety;
 - safety culture;
 - site characterization;
 - facility and system knowledge (design, operation and maintenance, including surveillance methods);
 - accident analysis;
 - emergency planning;
 - safety assessment;
 - decommissioning;
 - waste management and disposal;
 - quality assurance and organizational matters.

- Knowledge of regulatory policies and processes:
 - legislative aspects;
 - regulatory policy and its objectives;
 - regulations and use of regulatory guides;
 - authorization stages and procedures, including the purpose and content of supporting documentation;
 - internal guidance and procedures of the regulatory body;
 - methods of review and assessment;
 - inspection techniques;
 - enforcement procedures.

- Professional knowledge such as:
 - knowledge of regulatory control;
 - review and assessment skills;
 - inspection skills;
 - knowledge from job specific training;
 - knowledge from on the job training.

- Communication and management skills such as skills in respect of:
 - oral communication;
 - effective writing;
 - interviewing;
 - negotiation;
 - leadership;
 - project management;
 - teamwork;
 - decision making;
 - languages;
 - computer use;
 - public information.

- Continuing training:
 - refresher training;
 - further personal development.

- Information exchange and international co-operation.

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GLOSSARY

assessment. The process, and the result, of analysing systematically the hazards associated with sources and practices, and associated protection and safety measures, aimed at quantifying performance measures for comparison with criteria.

authorization. The granting by a regulatory body or other governmental body of written permission for an operator to perform specified activities. Authorization could include, for example, licensing, certification, registration, etc.

closure. Administrative and technical actions directed at a repository at the end of its operating lifetime — e.g. covering of the disposed waste (for a near surface repository) or backfilling and/or sealing (for a geological repository and the passages leading to it) — and termination and completion of activities in any associated structures.

commissioning. The process during which systems and components of facilities and activities, having been constructed, are made operational and verified to be in accordance with the design and to have met the required performance criteria.

decommissioning. Administrative and technical actions taken to allow the removal of some or all of the regulatory controls from a facility (except for a repository which is closed and not decommissioned).

enforcement. The application by a regulatory body of sanctions against an operator intended to correct and, as appropriate, penalize non-compliance with conditions of an authorization.

inspection. An examination, observation, measurement or test undertaken to assess structures, systems, components and materials, as well as operational activities, processes, procedures and personnel competence.

licence. A legal document issued by the regulatory body granting authorization to perform specified activities related to a facility or activity.

operator (operating organization). Any organization or person applying for authorization or authorized and/or responsible for nuclear, radiation, radioactive waste or transport safety when undertaking activities or in relation to any nuclear facilities or sources of ionizing radiation. This includes, inter

alia, private individuals, governmental bodies, consignors or carriers, licensees, hospitals, self-employed persons, etc.

regulatory body. An authority or a system of authorities designated by the government of a State as having legal authority for conducting the regulatory process, including issuing authorizations, and thereby regulating nuclear, radiation, radioactive waste and transport safety.

repository. A nuclear facility where waste is emplaced for disposal.

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